K124051

Section 510(k) Releasable Summary

MAY 17 2013

Proprietary Name: *VAULT® System Surgery Planning Software*

Common Name: Surgery Planning Software

Classification Name & CFR Reference: Sec. 892.2050 System, image processing, radiological

(a) ***Identification***. A picture archiving and communications system is a device that provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. Its' hardware components may include workstations, digitizers, communications devices, computers, video monitors, magnetic, optical disk, or other digital data storage devices, and hardcopy devices. The software components may provide functions for performing operations related to image manipulation, enhancement, compression or quantification.

(b) ***Classification***. Class II (special controls; voluntary standards-Digital Imaging and Communications in Medicine (DICOM) Std., Joint Photographic Experts Group (JPEG) Std., Society of Motion Picture and Television Engineers (SMPTE) Test Pattern).
[63 FR 23387, Apr. 29, 1998]

Regulatory Class: Class II

Device Product Code: LLZ

Company Contact:
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Date Prepared: April 12, 2013

Predicate Device(s):
1) Mimics Software – K073468
2) TraumaCAD Software– K073714

Summary Device Description: The VAULT® System software described here was developed in conformance with reference to the FDA Guidance Document for Industry "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, July 27, 2000". Based on the information contained in Section G of that document, a final determination of submission content was developed. A secondary reference entitled "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005 was also used and resulted in a determination of a "MODERATE" level of concern for the software.

The VAULT® System software is made available to the user via a web-accessed software interface. The program is a surgeon directed surgical planning package primarily but not exclusively directed at trauma and orthopedic indications. After secure log-in the user requests, creates, reviews and finally authorizes their desired surgical plan. When authorizing, the surgeon/user may choose additional options such as implant sizing and/or various file output options.

Discussion of Similarities and Differences: The primary and most immediately noticeable difference is that the VAULT® System software is Web-based while the predicate devices are local (PC/Laptop/Notebook) or local server based (hospital/clinic/office). Locally installed software presents minor to major complicating factors related to version, hardware, speed, operating system conflicts, etc. Those complicating factors are eliminated or reduced by direct company control of single edition server based web-portal program access. All users access the same optimized revision level software.

A second apparent difference in the basic operation of the Vault System and the predicate(s) software is the initial mass conversion and use of graphical images such as JPEG, BMP, PNG, of TIFF by the Vault System for planning. Both Mimics and TraumaCAD perform their planning on the DICOM images and then save/export files to JPEG file format(s) for presentation and export/import purposes.

The difference between the systems is the fact that the predicate software packages perform DICOM to JPEG conversion as a post-plan individual step. The VAULT® System software performs this activity initially, converting all image files at once before planning and saving or exporting. Functionally there is no significant difference between the program capabilities other than improved performance on the part of the VAULT® System software.

Feature	VAULT® System	Mimics K073468	TraumaCAD K073714
Indication for Use:	The VAULT® System is intended for use as a software interface and image manipulation system for the transfer of imaging information from a medical scanner such as Computerized Axial Tomography (CT) or Magnetic Resonance Imaging (MRI). It is also intended as pre-operative software for simulating/evaluating implant placement and surgical treatment options. The physician chooses the out-put data file for printing and/or subsequent use in CAD modeling or CNC/Rapid-prototyping.	Mimics software is intended for use as a software interface and image manipulation system for the transfer of imaging information from a medical scanner such as a CT scanner or Magnetic Resonance Imaging scanner to an output file. It is also intended as preoperative software for simulating / evaluating surgical treatment options. Mimics is not intended for mammography imaging.	The TraumaCAD program is indicated for assisting healthcare professionals in preoperative planning of orthopedic surgery. The device allows for overlaying of prosthesis templates on radiological images, and includes tools for performing measurements on the image and for positioning the template. Clinical judgments and experience are required to properly use the software.
Classification:	Class II	Class II	Class II
ProCode:	LLZ	LLZ	LLZ
Computer:	PC Compatible	PC & Workstation Compatible	PC Compatible
# of on-Screen Images	3	One	One
Runs on Server	Yes	Yes	Yes
Elective Procedures	Yes	Yes	Yes
Overlay & Templates	Yes	Yes	Yes
Preoperative Planning	Yes	Yes	Yes
Controls Life Saving Devices	No	No	No
Uses DICOM images	Yes	Yes	Yes
Expandability	Yes	Yes	Yes

Summary Non-Clinical Performance Data: Performance data were evaluated by conducting and repeating a defined series of objective and subjective test conditions. Results of this testing demonstrates that the VAULT® System provides an equivalent level of performance and clinical utility to the cited equivalent comparison software systems. Functional requirements as defined by the VAULT® System Software Requirements Specification (SRS) were tested and traceability was performed and documented using FDA's General Principles of Software Validation guidance document.

Safety requirements were developed using a safety risk/hazard analysis based on ISO 14971:2007 approach. Validation included boundary values and stress testing as defined by the FDA's Guidance for the Content of Premarket Submission for Software Contained in Medical Devices guidance document. Software testing addressed the following areas of functionally.

- Anatomical and phantom model digital file testing demonstrated the required level of accuracy and functionality.
- Digital file image upload controlled by DICOM process met specifications.

- Image file integrity, accuracy and suitability following required conversion, save and transfer operations met all specifications.
- Image calculations & measurement of anatomic features and landmarks meets specifications.

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Conclusion: Substantial equivalence is represented by comparison with the published capabilities of the predicate software devices. The referenced devices have equivalent uses, restrictions, clinical utility, safety and effectiveness to the VAULT® System. It is concluded that the VAULT® System may be reasonably expected to perform in a manner equivalent to the predicate devices. No new issues of either safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 17, 2013

Somersault Orthopedics, Inc.
% Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K124051
Trade/Device Name: Vault® System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 15, 2013
Received: April 19, 2013

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

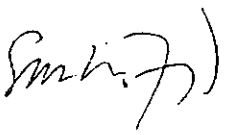
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K124051

Device Name: **VAULT® System**

Indications for Use:

The **VAULT® System** is intended for use as a software interface and image manipulation system for the transfer of imaging information from a medical scanner such as Computerized Axial Tomography (CT) or Magnetic Resonance Imaging (MRI). It is also intended as pre-operative software for simulating/evaluating implant placement and surgical treatment options. The physician chooses the out-put data file for printing and/or subsequent use in CAD modeling or CNC/Rapid-prototyping.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k): K124051